

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

 **EPA-HQ-OPP-2013-0226; FRL-XXXX-XX]Flupyradifurone; Pesticide**

Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of flupyradifurone, 4-[[[(6-chloro-3-pyridinyl)methyl](2,2-difluoroethyl)amino]- 2(5H)-furanone in or on multiple commodities which are identified and discussed later in this document. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2013-0226, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday,

excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are **an agricultural producer, food manufacturer, or pesticide manufacturer**. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- **Crop production (NAICS code 111).**
- **Animal production (NAICS code 112).**
- **Food manufacturing (NAICS code 311).**
- **Pesticide manufacturing (NAICS code 32532).**

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl**To**

access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.”

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number **EPA-HQ-OPP-2013-0226** in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number **EPA-HQ-OPP-2013-0226**, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of June 5, 2013 (78 FR 33785) (FRL-9386-2), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F8101) by Bayer CropScience LP, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the flupyradifurone, 4-[[[(6-chloro-3-pyridinyl)methyl](2,2-difluoroethyl)amino]- 2(5H)-furanone and its metabolites, difluoro acetic acid (DFA) and 4-[(2,2-difluoroethyl)amino]furan-2(5H)-one (DFEAF), in or on the following commodities: Aspirated Grains Fractions at 40 ppm; Root Vegetables Except Sugar Beets (Crop Subgroup 1B) at 1.5 ppm; Tuberous and Corm Vegetables; (Crop Subgroup 1C) at 0.5 ppm; Onion, bulb, subgroup, (Crop subgroup 3-07A at 0.3 ppm; Onion, green, subgroup, (Crop subgroup 3-07B) at 3 ppm; Leafy Vegetable, Except Brassica Vegetables (Crop Group 4) at 40 ppm; Taro Leaves at 40 ppm; Head and Stem Brassica (Crop Subgroup 5A) at 6 ppm; Leafy Brassica Greens (Crop Subgroup 5B) at 40 ppm; Turnip Greens at 40 ppm; Edible-Podded Legume Vegetables (Crop Subgroup 6A) at 5 ppm; Succulent, Shelled Pea and Bean (Crop Subgroup 6B) at 4 ppm; Dried, Shelled Pea and

Bean (Except Soybean) (Crop Subgroups 6C) at 6 ppm; Foliage of Legume vegetables, including soybeans (Crop Group 7), Forage, Green Vines at 40 ppm; Foliage of Legume vegetables, including soybeans (Crop Group 7), Hay at 50 ppm; Soybean, seed at 4 ppm; Fruiting Vegetables, Except Cucurbits (Crop Group 8-10), Fruit at 3 ppm; Tomato, paste at 4 ppm; Cucurbit Vegetables (Crop Group 9), Fruit at 2 ppm, Citrus Fruits (Crop Group 10-10), Fruit at 3 ppm; Citrus, pulp, dried at 15 ppm; Pome Fruits (Crop Group 11-10), Fruit at 1.5 ppm; Bushberry Subgroup (Crop Subgroup 13-07B) at 4 ppm; Small Fruit Vine Climbing Subgroup, Except Fuzzy Kiwifruit (Crop Subgroup 13-07F) at 3 ppm; Grapes, raisin at 6 ppm; Low Growing Berry Subgroup (Crop Subgroup 13-07G) at 1.5 ppm; Tree Nuts (Crop Group 14), Nutmeat at 0.15 ppm; Pistachio at 0.15 ppm; Tree Nuts (Crop Group 14), Hulls at 15 ppm; Grain, cereal, (Crop Group 15), except rice; grain at 4 ppm; Sweet Corn, kernels plus cobs with husks removed (K+CWHR) at 0.4 ppm; Wheat, bran at 5 ppm; Rice, grain (rotational crop) at 4 ppm; Grain, cereal, forage, fodder and straw, Group 16, forage at 20 ppm; Grain, cereal, forage, fodder and straw, Group 16, hay at 40 ppm; Grain, cereal, forage, fodder and straw, Group 16, straw at 30 ppm; Grain, cereal, forage, fodder and straw, Group 16, stover at 15 ppm; Cotton, undelinted seed, (Crop Subgroup 20C) at 0.9 ppm; Cotton, gin by- products at 40 ppm; Nongrass animal feeds, forage, (Crop Group 18) at 20 ppm; Nongrass animal feeds, hay, (Crop Group 18) at 40 ppm; Coffee, bean, green at 2 ppm; Coffee, bean, roasted; instant at 3 ppm; Hops at 20 ppm; Peanut, hay at 30 ppm; Peanut, nutmeat at 0.15 ppm; Prickly pear cactus, fruit; at 0.5 ppm; Pitaya, fruit at 0.5 ppm; Prickly pear cactus, pads at 0.9 ppm; Cattle, Goat, Hog, Horse, Sheep fat at 0.5 ppm; Cattle, Goat, Hog, Horse, Sheep meat at 1 ppm; Cattle, Goat, Hog, Horse, Sheep, meat byproducts at 2 ppm; Milk at 0.3 ppm, Poultry, eggs at 0.3 ppm, Poultry, meat at 0.5 ppm; Poultry, meat byproducts at 0.5 ppm.

That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed commodity definitions and altered tolerance levels for different commodities. EPA has reviewed the available residue data and has determined the appropriate tolerance levels for residues of flupyradifurone. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the

hazards of and to make a determination on aggregate exposure for flupyradifurone, including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with flupyradifurone, follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Flupyradifurone (BYI 02960) is a new butenolide insecticide. The most sensitive effects seen in the flupyradifurone database were skeletal muscle atrophy/degeneration in dogs. With repeated dosing, reductions in body weight and food consumption were commonly seen in various studies and in all species of test animals (rats, mice, dogs, and rabbits). The liver and thyroid were shown to be the common findings of flupyradifurone toxicity. The database appears to suggest that dogs are more sensitive to the effects of flupyradifurone; however, with body weight adjustments (based on a $\frac{3}{4}$ scaling factor), the dog and rat are almost equally as sensitive in response to flupyradifurone toxicity. The skeletal muscle atrophy/degeneration seen in the 90-day and one-year dog studies formed the basis for chronic dietary exposure toxicity endpoints.

The developmental toxicity study in rats demonstrated no evidence of susceptibility in developing animals. In the rabbit developmental toxicity study, there was an increase in the incidence of fetal death at 80 mg/kg/day (the highest dose tested), a dose that did not produce adverse effects in the maternal animals. Therefore, a

quantitative increase in susceptibility was demonstrated in the rabbit developmental toxicity study. In the 2-generation reproduction study in rats, decreased parental body weights ($\geq 10\%$) were seen at the LOAEL of 137 mg/kg/day (parental NOAEL = 37.8 mg/kg/day). In contrast, body weight decreases that were considered adverse were seen in F₂ pups at 37.8 mg/kg/day (the parental NOAEL and the offspring LOAEL; offspring NOAEL = 7.7 mg/kg/day). These findings suggest quantitative susceptibility for developing young animals.

The acute neurotoxicity study (dosing by gavage) showed that at the time of peak-effect, flupyradifurone caused increases in the incidence of piloerection and dilated pupils at 50 mg/kg. At the next higher dose level (200 mg/kg) and above, it produced a large host of clinical signs, which were related to neurotoxicity. The clinical signs included dilated pupils, lower muscle tone, low arousal, tremors, myoclonic jerks, chewing, repetitive licking of lips, gait incoordination, flattened or hunched posture, and impaired righting reflex. In the 90-day neurotoxicity study, no neurotoxicity or other adverse effects were seen at dose levels as high as 174 mg/kg/day. The developmental neurotoxicity study at 102 mg/kg/day yielded an increased incidence of increased amplitude in startle response.

Flupyradifurone is classified as “not likely to be carcinogenic to humans.” Carcinogenicity studies in rats and mice did not yield a compound-related increase in tumor incidence, and the genotoxicity battery did not show flupyradifurone to produce any genotoxicity.

Flupyradifurone did not demonstrate any immunotoxic effects.

Specific information on the studies received and the nature of the adverse effects caused by flupyradifurone as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document Human Health Risk Assessment at page 4 in docket ID number EPA-HQ-OPP-2013-0226.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for flupyradifurone used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for flupyradifurone, for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (All populations)	NOAEL = 35 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Acute RfD = .35 mg/kg/day	Acute neurotoxicity study – rat LOAEL = 50 mg/kg/day based on increased incidences of piloerection in both sexes and pupil dilation in females on Day 1. At the next higher dose level (200 mg/kg) or above, lower muscle tone, rapid respiration, low arousal, tremors, myoclonic jerks, chewing, repetitive licking of lips, gait incoordination, flattened or hunched posture, dilated pupils, impaired (uncoordinated or slow) righting reflex, impaired flexor and tail pinch responses and reduced rectal temperature. Automated measures of motor activity were also reduced in both sexes, compared to controls.
Chronic dietary (All populations)	NOAEL= 7.8 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = .078 mg/kg/day cPAD = .078 mg/kg/day	1-year oral toxicity study-dog LOAEL= 28 mg/kg/day based on minimal to slight, focal to multifocal areas of skeletal muscle degeneration in

			gastrocnemius and/or biceps femoris muscle.
Cancer (Oral, dermal, inhalation)	Flupyradifurone is classified as “not likely to be carcinogenic to humans” based on data showing no treatment related increase in tumor incidence in rat and mouse carcinogenicity studies.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to flupyradifurone, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from flupyradifurone, in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for flupyradifurone. Exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID). This software uses 2003-2008 food consumption data from the U.S. Department of Agriculture’s (USDA’s) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed that flupyradifurone residues were present at recommended tolerance levels in all commodities and that 100% of these crops were

treated with flupyradifurone. DEEM default processing factors were used for dried apple, dried beef, cranberry juice, and dried pear; empirical processing factors were used for processed commodities of apple (sauce and juice), coffee, citrus oil, cotton (oil), corn (bran, flour, meal, starch, oil), grape (wine, juice), grapefruit (juice), hops (dried cones), limes (juice), lemons (juice), oranges (juice and peel), peanut (butter, oil), pears (juice), potatoes (chips, flakes, cooked), tomatoes (juice, puree, paste), soybeans (oil, milk, flour), and wheat (bran, germ, flour).

ii. *Chronic exposure.* Exposure and risk assessments were conducted using the DEEM-FCID. This software uses 2003-2008 food consumption data from the USDA's NHANES/WWEIA. EPA assumed that flupyradifurone residues were present at recommended tolerance levels in all commodities and that 100% of these crops were treated with flupyradifurone. DEEM default processing factors were used for dried apple, dried beef, cranberry juice, and dried pear; empirical processing factors were used for processed commodities of apple (sauce and juice), coffee, citrus oil, cotton (oil), corn (bran, flour, meal, starch, oil), grape (wine, juice), grapefruit (juice), hops (dried cones), limes (juice), lemons (juice), oranges (juice and peel), peanut (butter, oil), pears (juice), potatoes (chips, flakes, cooked), tomatoes (juice, puree, paste), soybeans (oil, milk, flour), and wheat (bran, germ, flour).

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that flupyradifurone does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for

flupyradifurone. Tolerance-level residues and/or 100% CT were assumed for all food commodities.

2. Dietary exposure from drinking water.

The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for flupyradifurone, in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of flupyradifurone. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at

<http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) the estimated drinking water concentrations (EDWCs) of flupyradifurone for acute exposures is estimated to be 52.5 parts per billion (ppb) for surface water. Based on the Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of flupyradifurone for acute exposures are estimated to 352 ppb for ground water.

Based on the PRZM/EXAMS the EDWCs of flupyradifurone for chronic exposures for non-cancer assessments are estimated to be 22.3 ppb for surface water and based on the PRZM GW the EDWCs are estimated to be 307 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 352 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 307 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Flupyradifurone is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found **flupyradifurone** to share a common mechanism of toxicity with any other substances, and **flupyradifurone** does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that **flupyradifurone** does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website

at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different

margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. Prenatal and postnatal sensitivity. The developmental toxicity study in rats demonstrated no evidence of susceptibility in developing animals. In the rabbit developmental toxicity study, there was an increase in the incidence of fetal death at 80 mg/kg/day, a dose that did not produce adverse effects in the maternal animals. Therefore, a quantitative increase in susceptibility was demonstrated in the rabbit developmental toxicity study; however, the deaths occurred only at the highest tested dose. In the 2-generation reproduction study in rats, decreased parental body weights ($\geq 10\%$) were seen at the LOAEL of 137 mg/kg/day (parental NOAEL = 37.8 mg/kg/day). In contrast, body weight decreases that were considered adverse were seen in F₂ pups at 37.8 mg/kg/day (the parental NOAEL and the offspring LOAEL; offspring NOAEL = 7.7 mg/kg/day). These findings suggest quantitative susceptibility for developing young animals. However, the effects seen in the rabbit developmental study and in the rat reproductive study occurred at doses higher than the toxicity POD for risk assessment, which was selected from the 1-year dog study (28 mg/kg/day, LOAEL) with a NOAEL of 7.8 mg/kg/day. The NOAEL (7.8 mg/kg/day) selected as the POD for chronic dietary risk assessment is protective of the effects seen in the rat F₂ pups and the increased incidence of fetal death in the developmental rabbit study. Therefore, there are no concerns for the observed increased susceptibility.

3. Conclusion.

EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for flupyradifurone is complete.
- ii. Although there is evidence that flupyradifurone has neurotoxic effects, EPA has a complete set of neurotoxicity studies (acute, subchronic, and developmental). The effects of those studies are well-characterized and indicate neurotoxic effects that occur at levels above the chronic POD that was selected for risk assessment. The NOAEL for the acute neurotoxicity study is being used for the acute POD. Therefore, there is no need to retain the 10X FQPA safety factor to account for any uncertainty concerning these effects.
- iii. There is no evidence that flupyradifurone results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. There is quantitative susceptibility in rabbit developmental study and in the pup of the reproduction study, but the PoDs are protective of this increased susceptibility.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to flupyradifurone in drinking water. These assessments will not underestimate the exposure and risks posed by flupyradifurone.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.*

Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to flupyradifurone will occupy 38% of the aPAD for children 1-2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.*

Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to flupyradifurone from food and water will utilize 84% of the cPAD for children 1-2 years old the population group receiving the greatest exposure. There are no residential uses for flupyradifurone.

3. *Short-term and Intermediate-term risk.* Short-term and Intermediate-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short-term/intermediate-term adverse effect was identified; however, flupyradifurone is not registered for any use patterns that would result in short-term or intermediate-term residential exposure. Because there is no short-term or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term

risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for flupyradifurone.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, flupyradifurone is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to flupyradifurone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography with tandem mass spectrometry (HPLC/MS-MS)) is available to enforce the tolerance expression. The validated limit of quantification (LOQ) is 0.01 mg/kg for flupyradifurone in most commodities.

An HPLC/MS/MS method, Method RV-004-A11-05 (latest revision of the data collection method RV-004-A11-04), is adequate as the enforcement method for determination of residues of flupyradifurone in livestock commodities. The validated LOQ for flupyradifurone is 0.01 mg/kg in all matrices.

FDA multiresidue methods (MRMs) are suitable for flupyradifurone only in non-fatty matrices. The methods are not suitable for fatty matrices or matrices that require further clean-up. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCa section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCa section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRLs for flupyradifurone.

C. Revisions to Petitioned-For Tolerances

The Petitioner requested a definition for enforcement of tolerance as the sum of flupyradifurone and difluoro acetic acid (DFA) and 4-[(2,2-difluoroethyl)amino]furan-2(5H)-one (DFEAF), expressed as flupyradifurone, which significantly inflated the field trial residue values and resulted in higher tolerance values. EPA, consistent with its global review partners, has selected parent flupyradifurone only as the residue definition for tolerance enforcement. Flupyradifurone is the major portion of the residue in plant commodities and in some livestock commodities. In other livestock commodities, it is present at the same approximate concentration as some metabolites. Moreover, the significant metabolite difluoroacetic acid (DFA) is not suitable for enforcement purposes, as its concentration is erratic with time. The harmonized enforcement definition,

flupyradifurone only, will facilitate trade and is predicted to be the residue definition adopted by Codex in the future based on application of their policy. Therefore, EPA is reducing the tolerance values for the petitioned-for tolerances for the following commodity groups/subgroups or commodities: **cattle, goat, hog, horse, and sheep meat and meat byproducts; hog fat; milk; poultry eggs;** root vegetables subgroup 1B; tuberous and corm vegetables subgroup 1C; bulb onion subgroup 3-07A; leafy vegetable group 4; legume vegetables subgroups 6A, 6B, 6C; soybean; foliage of legume vegetables group 7; fruiting vegetables group 8-10; cucurbit vegetables group 9; citrus pulp; pome fruits group 11-10; grape raisins; bushberry subgroup 13B except cranberry; tree nut group 14; cereal grain group 15 except rice and except corn; sweet corn, cereal grain forage, fodder, and straw group 16; nongrass animal feeds crop group 18; cotton undelinted seed; coffee bean; hops; peanut hay; peanut; prickly pear cactus fruit and pad.

The petition requested a tolerance for root vegetables, except sugar beets subgroup 1B at 1.5 ppm. The ratio of highest average field trials (HAFTs) of the representative commodities (carrot/radish, 0.603/0.046 ppm) was 13, but the ratio of the median residue value was 1.8. The small median ratio indicates that the central tendency of both carrot and radish residue values are similar and that a single tolerance would be appropriate for the subgroup, represented by carrot and radish. The higher tolerance estimate from carrot (0.90 ppm) will cover all members of the subgroup.

The petition requested a tolerance for the leafy vegetable, except brassica vegetables, group 4 at 40 ppm. Based on the available residue data, EPA is establishing separate tolerances for each of the subgroups of group 4, instead of a single tolerance for the whole group. For subgroup 4A (leafy greens), EPA is establishing a tolerance at 30

ppm, based on the highest residues, which were found on the representative crop spinach. For subgroup 4B (leafy petioles), EPA is establishing a separate tolerance at 9.0 ppm based on the celery residues. The leafy greens subgroup tolerance was translated to cover taro leaves; therefore, EPA is establishing a tolerance for taro leaves at 30 ppm, rather than the 40 ppm requested.

The petitioned-for tolerance for the shelled pea and bean subgroup 6B at 4 ppm was not possible because the residues on the garden pea and lima bean were substantially different. Residues differ by more than 5X between succulent peas and succulent beans. In accordance with 40 CFR 180.40(g), a subgroup tolerance is not normally appropriate; rather, EPA may establish individual crop tolerances. Therefore, EPA is establishing individual tolerances for succulent peas and succulent beans.

The petition requested a tolerance for cereal grains, grain, group 15 except rice at 4 ppm. The residues on sweet corn and field corn grain were much lower than those on sorghum, wheat, and barley grains; therefore, EPA is excluding corn (field corn, popcorn, and sweet corn) grain from that group 15 tolerance, as well as rice. Based on available residue data, EPA is establishing separate tolerances for popcorn, grain, field corn, grain, and sweet corn (kernels plus cobs with husks removed) at 0.05 ppm. Under 180.40(h), EPA may exclude some commodities from a group tolerance where the residue levels are significantly higher or lower than the other commodities in the group. Corn, unlike the other cereal grains, has a protective husk and this difference is often reflected in lower residues for late season foliar applications. Therefore, EPA is excluding corn grain and rice from the crop group 15 tolerance and establishing separate tolerances for corn. The

remaining cereal grains, represented by grain sorghum, barley, and wheat, are quite similar.

The petition requested a tolerance on nongrass animal feeds group 18, forage at 20 ppm and hay at 40 ppm. EPA is unable to establish group 18 tolerances at this time for forage and hay because data from only four field trials on clover (one of the representative crops) was available. Based on the available data, EPA is establishing tolerances for alfalfa and regional tolerances for clover (since use on clover is restricted to Washington, Oregon, and Idaho, the area where the field trials were conducted). A group tolerance could be considered if additional field trials for clover from diverse areas of the US were supplied.

The petition requested a tolerance for rice grain at 4 ppm as a rotational crop. EPA cannot establish this tolerance at this time because no data were provided to support this request. Rice field trial data are required to establish a tolerance.

The proposed wheat bran tolerance of 5 ppm is not necessary. The cereal grain group tolerance covers wheat bran. The highest average field trial (HAFT) residue for wheat grain was 0.73 ppm and the experimentally determined processing factor for the conversion of grain to bran was 2.4. Therefore, the tolerance estimate for wheat bran is 1.8 ppm (0.73×2.4). As 1.8 ppm is less than the 3 ppm cereal group tolerance, a separate tolerance for wheat bran is not needed.

EPA was petitioned for tolerances on tree nut group 14 and pistachio. In the Federal Register of August 22, 2012 (77 FR 50617) (FRL-9354-3), EPA issued a final rule that revised the crop grouping regulations. As part of this action, EPA expanded and revised the existing tree nut group 14. Changes to crop group 14 included adding the

specialty commodities African nut tree, Brazilian pine, Bunya, Bur oak, Cajou nut, Candlenut, Coconut, Coquito nut, Dika nut, Ginkgo, Guiana chestnut, Heartnut, Japanese horse-chestnut, Mongongo nut, Monkey-pot, Monkey puzzle nut, Okari nut, Pachira nut, Peach palm nut, Pequi, Pili nut, Pine nut, Pistachio, Tropical almond and Yellowhorn including cultivars, varieties, and/or hybrids of these; and naming the new crop group tree nut group 14–12. EPA indicated in the August 22, 2012 final rule as well as the earlier November 9, 2011 proposed rule (76 FR 69693) (FRL–8887–8) that, for petitions for which a Notice of Filing had been published, the Agency would attempt to conform these petitions to the rule. Therefore, consistent with this rule, EPA has assessed exposure to the, insecticide flupyradifurone, assuming use under the revised tree nut group 14-12. Because revising the requested crop group to the updated crop group did not result in a risk of concern, EPA is establishing tolerances for flupyradifurone residues on tree nut group 14–12.

Cranberry was removed from subgroups 13-07B and 13-07G at the request of the petitioner as a modification to the original request.

Tolerances are not needed for the processed commodities tomato paste, roasted coffee, and instant coffee. The recommended tolerances for the raw agricultural commodities, tomato and green coffee bean cover the respective processed commodities. The highest average field trial (HAFT) result for coffee was 0.55 ppm, and the processing factors for roasted coffee and instant coffee were 0.59 and 1.9, respectively. Tolerance estimate (HAFT X processing factor; $0.55 \times 0.59 = 0.32$ ppm roasted bean; $0.55 \times 1.9 = 1.0$ ppm instant coffee) are less than the recommended green coffee bean tolerance (1.5 ppm). The HAFT for the tomato field trials was 0.57 ppm and the processing factor for

conversion to paste was 2.0, and the product (0.57X2.0) is less than the recommended fruiting vegetable group tolerance (1.5 ppm).

Tolerances are not required for poultry meat and poultry meat byproducts, as the projected diet for poultry and the results of the poultry feeding study indicate that residues are not likely in poultry meat and poultry meat byproducts.

V. Conclusion

Therefore, tolerances are established for residues of flupyradifurone, 4-[[[(6-chloro-3-pyridinyl)methyl](2,2-difluoroethyl)amino]- 2(5H)-furanone are, Alfalfa, forage at 9.0 ppm; Alfalfa, hay at 20 ppm; Almond, hulls at 15 ppm; Bean, succulent at 0.2 ppm; Berry, low growing, subgroup 13-07G, except cranberry at 1.5 ppm; Brassica, head and stem, subgroup 5A at 6.0 ppm; Brassica, leafy greens, subgroup 5B at 40 ppm; Bushberry subgroup 13-07B, except cranberry at 4.0 ppm; Cactus, fruit at 0.30 ppm; Cactus, pads at 0.70 ppm; Vegetable, root, except sugar beet, subgroup 1B at 0.9 ppm; Cattle, fat at 0.20 ppm; Cattle, meat at 0.30 ppm; Cattle, meat byproducts at 1.0 ppm; Clover, forage at 20 ppm; Clover, hay at 30 ppm; Coffee, green bean at 1.5 ppm; Corn, field, grain at 0.05 ppm; Corn, pop, grain at 0.05 ppm; Corn, sweet, kernels plus cobs with husks removed at 0.05 ppm; Cotton, gin byproducts at 40 ppm; Cottonseed subgroup 20C at 0.80 ppm; Egg at 0.01 ppm; Fruit, citrus, group 10-10 at 3.0 ppm; Citrus fruit, citrus, dried pulp, at 10 ppm; Fruit, pome, group 11-10 at 0.70 ppm; Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 3.0 ppm; Goat, fat at 0.20 ppm; Goat, meat at 0.30 ppm; Goat, meat byproducts at 1.0 ppm; Grain, aspirated grains fractions at 40 ppm; Grain, cereal, except rice and corn, group 15 at 3.0 ppm; Grain, cereal, forage, fodder and straw, group 16 at 30 ppm; Grape, raisin at 5.0 ppm; Hog, fat at 0.01 ppm; Hog, meat at 0.01 ppm; Hog, meat byproducts at 0.04 ppm; Hops, dried cones 10 ppm; Horse, fat at 0.20

ppm; Horse, meat at 0.30 ppm; Horse, meat byproducts at 1.0 ppm; Leaf petioles, subgroup 4B at 9.0 ppm; Leafy greens, subgroup 4A at 30 ppm; Milk at 0.15 ppm; Nut, tree, group 14-12 at 0.02 ppm; Onion, bulb, subgroup 3-07A at 0.09 ppm; Onion, green, subgroup 3-07B at 3.0 ppm; Pea and bean, dried, shelled except soybean, subgroup 6C at 3.0 ppm; Pea, succulent at 2.0 ppm; Peanut at 0.04 ppm; Peanut, hay at 20 ppm; Pitaya at 0.30 ppm; Sheep, fat at 0.2 ppm; Sheep, meat at 0.30 ppm; Sheep, meat byproducts at 1.0 ppm; Soybean, seed at 1.5 ppm; Taro leaves at 30 ppm; Turnip greens at 40 ppm; Vegetable, cucurbit, group 9 at 0.40 ppm; Vegetable, fruiting, group 8-10 at 1.5 ppm; Vegetable, legume, edible podded, subgroup 6A at 3.0 ppm; Vegetable, tuberous and corm, subgroup 1C at 0.05 ppm; Vegetable, foliage of legume, group 7, at 30 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under

Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

Directions

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: _____

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

Click -- Select Option

2. In § 180.XX add alphabetically the following commodities to the table in paragraph to read as follows:

(a) *General.* Tolerances are established for residues of the insecticide

flupyradifurone, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only flupyradifurone, 4-[[[(6-chloro-3-pyridinyl)methyl](2,2-difluoroethyl)amino]- 2(5H)-furanone.

Commodity	Parts per million
Alfalfa, forage	9.0
Alfalfa, hay	20
Almond, hulls	15
Bean, succulent	0.20
Berry, low growing, except cranberry subgroup 13-07G	1.5
Brassica, head and stem subgroup 5A	6.0
Brassica, leafy greens subgroup 5B	40
Bushberry, except cranberry subgroup 13-07B	4.0
Cactus, fruit	0.30
Cactus, pads	0.70
Cattle, fat	0.20
Cattle, meat	0.30
Cattle, meat byproducts	1.0
Coffee, green bean*	1.5
Corn, field, grain	0.05
Corn, pop, grain	0.05
Corn, sweet, kernels plus cobs with husks removed	0.05
Cotton, gin byproducts	40

Cottonseed subgroup 20C	0.80
Egg	0.01
Fruit, citrus, group 10-10	3.0
Fruit, citrus, dried pulp	10
Fruit, pome group, 11-10	0.70
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F	3.0
Goat, fat	0.20
Goat, meat	0.30
Goat, meat byproducts	1.0
Grain, aspirated grain fractions	40
Grain, cereal, group 15, except rice and corn	3.0
Grain, cereal, forage, fodder and straw, group 16	30
Grape, raisin	5.0
Hog, fat	0.01
Hog, meat	0.01
Hog, meat byproducts	0.04
Hops, dried cones	10
Horse, fat	0.20
Horse, meat	0.30
Horse, meat byproducts	1.0
Leaf petioles subgroup 4B	9.0
Leafy greens subgroup 4A	30
Milk	0.15
Nut, tree, group 14-12	0.02
Onion, bulb subgroup,3-07A	0.09
Onion, green subgroup 3-07B	3.0
Pea and bean, dried, shelled except soybean subgroup 6C	3.0
Pea, succulent	2.0
Peanut	0.04
Peanut, hay	20
Pitaya	0.30
Sheep, fat	0.20
Sheep, meat	0.30
Sheep, meat byproducts	1.0
Soybean, seed	1.5
Taro leaves	30
Turnip greens	40
Vegetable, cucurbit, group 9	0.40
Vegetable, fruiting, group 8-10	1.5
Vegetable, legume, edible podded subgroup 6A	3.0
Vegetable, root, except sugar beet, subgroup 1B	0.90

Vegetable, tuberous and corm subgroup 1C	0.05
Vegetable, foliage of legume, group 7	30

* No U.S. registration

(b) Section 18 Emergency Exemptions [Reserved]

(c) Tolerances with regional restrictions: Tolerances are established for residues of the insecticide flupyradifurone, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only flupyradifurone, 4-[[[6-chloro-3-pyridinyl)methyl](2,2-difluoroethyl)amino]- 2(5H)-furanone.

Commodity	Parts per million
Clover, forage	20
Clover, hay	30

(d) Indirect or Inadvertent Residues [Reserved]